

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 50623.00887	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/US2007/011177	International filing date (day/month/year) 08/05/2007	(Earliest) Priority Date (day/month/year) 22/05/2006
Applicant ABBOTT CARDIOVASCULAR SYSTEMS INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.



It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of:



the international application in the language in which it was filed



a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

- b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6b/(a)).
- c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.
2. ☐ **Certain claims were found unsearchable** (See Box No. II)
3. ☐ **Unity of invention is lacking** (see Box No. III)

4. With regard to the **title**,

the text is approved as submitted by the applicant



the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

the text is approved as submitted by the applicant



the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings**,

- a. the figure of the **drawings** to be published with the abstract is Figure No. 3



as suggested by the applicant



as selected by this Authority, because the applicant failed to suggest a figure



as selected by this Authority, because this figure better characterizes the invention

- b. ☐ none of the figures is to be published with the abstract

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2007/011177

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61L31/02 A61L31/14

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2005/209680 A1 (GALE DAVID C [US] ET AL) 22 September 2005 (2005-09-22) page 2, paragraph 11 page 3, paragraph 29 page 4, paragraph 30 - paragraph 31 page 5, paragraph 38 - paragraph 39 -----	1-21
X	US 2002/082679 A1 (SIRHAN MOTASIM [US] ET AL) 27 June 2002 (2002-06-27) page 3, paragraph 23 page 5, paragraph 47 - paragraph 49 page 6, paragraph 55 page 13, paragraph 122 ----- -/-	1,8-11

☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents:

A document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the international filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

I later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

G document member of the same patent family

Date of the actual completion of the international search

30 July 2008

Date of mailing of the international search report

11/08/2008

Name and mailing address of the ISA/
European Patent Office, P.B. 5818 Patentaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,

Authorized officer

Fernando v. Carretero

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2007/011177

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/088038 A1 (DEHNAD HOUDIN [US] ET AL) 6 May 2004 (2004-05-06) page 2, paragraph 10 - paragraph 12 page 3, paragraph 20 page 5, paragraph 37 -----	17-21
P, X	US 2006/229711 A1 (YAN JOHN [US] ET AL) 12 October 2006 (2006-10-12) page 2, paragraph 16 - paragraph 21 page 3, paragraph 24 - paragraph 26 page 5, paragraph 60 - paragraph 66 page 6, paragraph 75 page 7, paragraph 89 page 8, paragraph 94 - paragraph 101 page 9, paragraph 108 -----	1-21
A	US 6 287 332 B1 (BOLZ ARMIN [DE] ET AL) 11 September 2001 (2001-09-11) column 2, line 26 - line 44 column 3, line 11 - line 40; examples 1-3 -----	1-21
A	US 2002/004060 A1 (HEUBLEIN BERND [DE] ET AL) 10 January 2002 (2002-01-10) page 1, paragraph 11 - paragraph 14 -----	1-21

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2007/011177

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 2005209680	A1	22-09-2005	US 2007282427 A1	06-12-2007
US 2002082679	A1	27-06-2002	NONE	
US 2004088038	A1	06-05-2004	NONE	
US 2006229711	A1	12-10-2006	NONE	
US 6287332	B1	11-09-2001	EP 0966979 A2	29-12-1999
US 2002004060	A1	10-01-2002	AT 297767 T	15-07-2005
			AT 236667 T	15-04-2003
			AU 9154198 A	10-02-1999
			DE 19731021 A1	21-01-1999
			WO 9903515 A2	28-01-1999
			EP 0923389 A2	23-06-1999
			ES 2243635 T3	01-12-2005
			ES 2200368 T3	01-03-2004
			JP 2001511049 T	07-08-2001
			PT 1270023 T	31-10-2005

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/US2007/011177

International filing date (day/month/year)
08.05.2007

Priority date (day/month/year)
22.05.2006

International Patent Classification (IPC) or both national classification and IPC
INV. A61L31.02 A61L31/4

Applicant
ABBOTT CARDIOVASCULAR SYSTEMS INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:

Date of completion of
this opinion

Authorized Officer



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NL-2280 HV Rijswijk - Pays Bas
Tel: +31 70 340 - 2040 Tlx: 31 651 eep nl
PCT/ISA/210

Espinosa y Carretero



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2007/011177

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in electronic form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

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Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	
	No: Claims	<u>1-21</u>
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-21</u>
Industrial applicability (IA)	Yes: Claims	<u>1-21</u>
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rules 43bis.1 and 70.10)

and / or

2. Non-written disclosures (Rules 43bis.1 and 70.9)

see form 210

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item V

**Reasoned statement with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

1. Reference is made to the following documents:

- D1: US 2005/209680 A1 (GALE DAVID C [US] ET AL) 22 September 2005 (2005-09-22)
- D2: US 2002/082679 A1 (SIRHAN MOTASIM [US] ET AL) 27 June 2002 (2002-06-27)
- D3: US 2004/088038 A1 (DEHNAD HOUDIN [US] ET AL) 6 May 2004 (2004-05-06)
- D4: US 2006/229711 A1 (YAN JOHN [US] ET AL) 12 October 2006 (2006-10-12)

2. Novelty

Document D1 discloses implantable medical devices, such as stents, that include a metallic region composed of a bioerodable metal and a polymer region composed of a biodegradable polymer contacting the metallic region (see page 2, paragraph [11]). Examples of biodegradable metals include magnesium, zinc and iron (see page 3, paragraph [29]). The metallic region may be a pure metal or a mixture that includes two types of metals (see page 5, paragraph [38]) and it may comprise pores (see claim 13). Therefore the subject-matter of claims 1-21 is not new according to Article 33(2) PCT.

Document D2 discloses medical devices such as stents which are formed of metals or alloys degradable in the body (see page 3, paragraph [23]) with small pits or pin holes to accelerate corrosion (see page 6, paragraph [55]). The stent may be coated with a polymeric material and a therapeutic agent (see page 5, paragraph [49]). Therefore the subject-matter of claims 1, 8-11 is not new according to Article 33(2) PCT.

Document D3 discloses porous metal stents for controlled release of therapeutic drugs, formed from a material selected from the group consisting of stainless steel, titanium, tantalum, nickel-titanium, cobalt-chromium, and alloys thereof (see claim 6) and having a polymeric coating.

**WRITTEN OPINION OF THE
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AUTHORITY (SEPARATE SHEET)**

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Therefore the subject-matter of claims 17-21 is not new according to Article 33(2) PCT.

Re Item VI

Certain documents cited

Certain published documents

Application No Patent No	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
US2006/0229711	12/10/2006	04/04/2006	05/04/2005

D4 may become relevant in the subsequent national/regional phase. The priorities have not been checked.

Re Item VIII

Certain observations on the international application

1. It is clear from the whole description that the following feature is essential to the definition of the invention:

(1) biodegradable

Since independent claims 12 and 17 do not contain this feature it does not meet the requirement following from Article 6 PCT taken in combination with Rule 6.3(b) PCT that any independent claim must contain all the technical features essential to the definition of the invention.

**WRITTEN OPINION OF THE
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AUTHORITY (SEPARATE SHEET)**

International application No.

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2. Although claims 1, 12 and 17 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought and in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack conciseness and as such do not meet the requirements of Article 6 PCT.

3. Claims 2, 6 and 17 do not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The claim attempt to define the subject-matter in terms of the result to be achieved, which merely amounts to a statement of the underlying problem, without providing the technical features necessary for achieving this result.

Possible steps after receipt of the international search report (ISR) and written opinion of the International Searching Authority (WO-ISA)

General information	For all international applications filed on or after 01/01/2004 the competent ISA will establish an ISR. It is accompanied by the WO-ISA. Unlike the former written opinion of the IPEA (Rule 66.2 PCT), the WO-ISA is not meant to be responded to, but to be taken into consideration for further procedural steps. This document explains about the possibilities.
Amending claims under Art. 19 PCT	Within 2 months after the date of mailing of the ISR and the WO-ISA the applicant may file amended claims under Art. 19 PCT directly with the International Bureau of WIPO. The PCT reform of 2004 did not change this procedure. For further information please see Rule 46 PCT as well as form PCT/ISA/220 and the corresponding Notes to form PCT/ISA/220.
Filing a demand for international preliminary examination	<p>In principle, the WO-ISA will be considered as the written opinion of the IPEA. This should, in many cases, make it unnecessary to file a demand for international preliminary examination. If the applicant nevertheless wishes to file a demand this must be done before expiry of 3 months after the date of mailing of the ISR/ WO-ISA or 22 months after priority date, whichever expires later (Rule 54bis PCT). Amendments under Art. 34 PCT can be filed with the IPEA as before, normally at the same time as filing the demand (Rule 66.1 (b) PCT).</p> <p>If a demand for international preliminary examination is filed and no comments/amendments have been received the WO-ISA will be transformed by the IPEA into an IPRP (International Preliminary Report on Patentability) which would merely reflect the content of the WO-ISA. The demand can still be withdrawn (Art. 37 PCT).</p>
Filing informal comments	After receipt of the ISR/WO-ISA the applicant may file informal comments on the WO-ISA directly with the International Bureau of WIPO. These will be communicated to the designated Offices together with the IPRP (International Preliminary Report on Patentability) at 30 months from the priority date. Please also refer to the next box.
End of the international phase	At the end of the international phase the International Bureau of WIPO will transform the WO-ISA or, if a demand was filed, the written opinion of the IPEA into the IPRP, which will then be transmitted together with possible informal comments to the designated Offices. The IPRP replaces the former IPER (international preliminary examination report).
Relevant PCT Rules and more information	Rule 43 PCT, Rule 43bis PCT, Rule 44 PCT, Rule 44bis PCT, PCT Newsletter 12/2003, OJ 11/2003, OJ 12/2003